

Food and Drug Administration

Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science

DAY 2: May 4, 2005

Questions

Topic# 2: Our initial thoughts – Are we on the right tract?

1. How can pharmaceutical development information help to extend the applications of BCS-based waiver of in vivo studies for immediate release products?
2. How can pharmaceutical development information be utilized to address the challenge of highly variable drugs?
3. Establishing therapeutic equivalence of topical products?

Topic# 3

Does the ACPS support the creation of a subcommittee under ACPS to develop the criteria and the process for review of OPS research programs?